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December 6, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: DOCKET NO. 97N-484S

Dear Sirs:

This letter is written in regards to Docket No. 97N-484S, the proposed FDA regulation making allograft bone which is currently classified as tissue to be changed to a medical device. I practice general neurosurgery in Anderson, South Carolina, and frequently use allograft bone for spinal fusions. I believe that changing allograft bone to a medical device and subjecting it to clinical trials and requiring bone banks to perform these trials and submit the regulatory documents will tax their assets and unnecessarily increase the cost of allograft bone. The expenses will also limit access to these types of tissues for patient use. Current state of this tissue is on very high demand due to its proven effective use in clinical settings for spinal fusion. Having regularly available allograft bone is the mainstay to effective efficient practice of neurosurgery. I think by changing the class from tissue to a medical device will subject this product to unnecessary testings as history has already proven it to be a safe and effective product.

I am writing this to formally lodge a complaint to this proposed FDA regulation.

Sincerely,

Aaron C. MacDonald, M.D.

ACM/pwc

97N-484S

C66

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Neurosurgical
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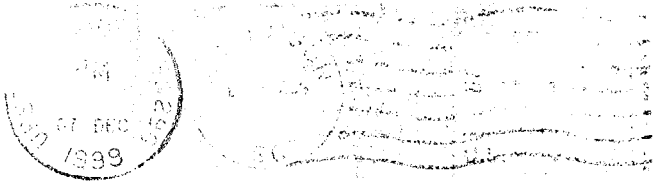

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